SUMMARY MINUTES

OF THE

CIRCULATORY SYSTEM DEVICES

ADVISORY PANEL MEETING

OPEN SESSION

DECEMBER 4-5, 2000

Gaithersburg Holiday Inn
Two Montgomery Village Avenue
Gaithersburg, MD

CIRCULATORY SYSTEM DEVICES ADVISORY PANEL MEETING

December 4-5, 2000

ATTENDEES

ACTING CHAIRPERSON

Cynthia M. Tracy, M.D.
Georgetown University Hospital

EXECUTIVE SECRETARY

Megan Moynahan, M.S.
Food and Drug Administration

VOTING MEMBERS

Michael D. Crittenden, M.D.
Harvard University

Renee Hartz, M.D.
Tulane Medical Center

CONSULTANTS (with Temporary Voting Status)

Salim Aziz, M.D.
University of Colorado

Michael Domanski, M.D.
NHLBI

Mitchell Krucoff, M.D.
Duke University Medical Center

Warren Laskey, M.D.
University of Maryland School of Medicine

Stephen Li, Ph.D. (December 4 session only)
Hospital for Special Surgery

Tony W. Simmons, M.D.
Wake Forest University/Baptist Medical Center

CONSUMER REPRESENTATIVE
Robert A. Dacey

INDUSTRY REPRESENTATIVE
Gary Jarvis
St. Jude Medical

FOOD AND DRUG ADMINISTRATION

James E. Dillard III
Donna-Bea Tillman, Ph.D.
Bram Zuckerman, M.D.
Russell P. Pagano
Chris M. Sloan
Lynette A. Gabriel
Doris J. Terry
Stuart M. Portnoy, M.D.
George H. Koustenis

OPEN SESSION—DECEMBER 4, 2000

Cynthia M. Tracy, M.D., Acting Panel Chairperson, called the Open Session to order at 10:04 a.m. **Executive Secretary Megan Moynahan** read the conflict of interest statement, noting that matters concerning Cynthia M. Tracy, M.D., Warren Laskey, M.D., Mitchell Krucoff, M.D., and Stephen Li, Ph.D., had been considered but deemed unrelated and their full participation would be allowed. **Dr. Tracy** asked the panel to introduce themselves and state their areas of expertise. **Ms. Moynahan** read appointments to temporary voting status for Cynthia M. Tracy, M.D., Salim Aziz, M.D., Warren Laskey, M.D., Tony Simmons, M.D., Mitchell Krucoff, M.D., Michael Domanski, M.D., and Stephen Li, Ph.D. and an appointment to serve as acting chairperson for Dr. Tracy.

OPEN PUBLIC HEARING

Bernadette Low of Guidant Corporation stated that Guidant had reviewed the petition to downclassify percutaneous transluminal coronary angioplasty (PTCA) catheters from class III to class II and was opposed on the grounds that reclassification would lead to an erosion of validation study standards, insufficient controls, and ultimately a reduction in product quality. She noted that these produces are still classified as high risk in Europe, Canada, and Japan, and that because PTCA catheter systems are used as the delivery vehicle for stents, changing the classification may have an impact on stent delivery system design, testing, and quality.

Reclassification would also delay the timeline for catheters having to meet FDA guidelines on reuse and would require less stringent evidence establishing safety of refurbished devices.

Panel Executive Secretary Megan Moynahan noted that two letters had been submitted to the FDA regarding the proposed reclassification and were available both in the panel pack and as part of the official record. She summarized a letter from **Boston Scientific,** which agreed that standard PTCA catheters are well established in the medical community and that there is sufficient clinical evidence to support downclassification of the devices. It stated that downclassification should apply to standard PTCA catheters only and agreed with the proposed device description, making minor modifications to the identified health risks. The letter also provided additional comments on the guidance documents. The second letter, from **Spectranetics Corporation,** agreed with the proposed reclassification but recommended that a standard definition of balloon PTCA catheter should be developed to differentiate it from other catheter devices. It identified additional health risks and suggested addressing potential damage to stents by balloon catheters, as well as recommending development of detailed labeling and revised guidelines.

Chris Sloan, Branch Chief of the Interventional Cardiology Devices Branch (FDA) gave the branch update. He noted that on June 19, 2000, the panel had recommended the Cordis Checkmate device as approvable subject to conditions of modified labeling, modifications to proposed physician training programs, and collection of five-year follow-up data. On November 3, 2000, the FDA approved the Checkmate device. Mr. Sloan also reported that at its September

11, 2000 meeting, the panel had recommended the Novoste Corporation's Beta-Cath intravascular brachytherapy device as approvable subject to conditions of additional labeling, modifications to training programs, five-year follow-up data, and a prospective postapproval study at new clinical sites. On November 3, 2000, the FDA approved the Beta-Cath device.

FDA Introductory Remarks

Lynette Gabriel, FDA reviewer summarized the regulatory history of PTCA catheters, noting that these devices are now class III devices subject to the premarket approval application (PMA) regulatory process and that 20 original PMAs and 820 PMA supplements have been approved since the first PMA was received in 1979. The petition under discussion seeks downclassification of PTCA catheters to class II devices subject to special controls. She read the proposed device description and indication for use, noting that reclassification applies only to the described devices for the approved indication for use, not to the entire product code. Stent delivery catheters, for example, are not within the described parameters of the category for proposed downclassification. Ms. Gabriel listed types of adverse events listed for the device in the Manufacturers and Users Device Event (MAUDE) Database, saying that from July 1996 through October 2000 there have been more than 3,000 reports. Comments the FDA has received regarding the downclassification petition have included the two letters summarized above, which agree with the proposal but stress that reclassification should apply only to "standard" PTCA catheters and express concern about use of PTCA catheters to treat in-stent restenosis. Both recommend revision of the FDA guidance document.

Sponsor Presentation

Cass Pinkerton, M.D., of Nasser, Smith, & Pinkerton Cardiology, reviewed the history of angioplasty, the evolution of the PTCA balloon catheter, and the labeling information needed by the physician. He outlined the history of cardiac catheterization from its inception in 1929 and described the types of PTCA balloon catheter. Some 200 catheters have been approved from a wide range of companies. Different materials such as nylon and PTE have been used to deal with different levels of lesions; clinicians need labeling information on balloon length, diameter, catheter length, lumen diameter, compliance, and burst pressure. Dr. Pinkerton concluded that PTCA catheters are a mature technology, although materials may continue to improve. Risks are known, although the incidence of each risk may vary due to many clinical and angiographic factors, and interventionalists need specific labeling information to minimize the potential for risks.

Neal Fearnot, Ph.D., president of MED Institute, Inc., discussed reasons for the reclassification petition, saying that one reason his company chose to sponsor the petition for reclassification was to free FDA resources to concentrate on other novel areas. He listed potential benefits to the procedure and read three indications for the PTCA device, noting that more than 400,000 PTCAs are used in the United States per year and more than 1 million PTCAs worldwide. He stated that there is a good understanding of the device and its use in interventional procedures, citing a number of studies on long-term results.

Dr. Fearnot said that special controls to address the risks of a standard PTCA catheter include guidance documents, labeling, design validation testing, and postmarket surveillance. Dr. Fearnot listed the guidances that exist now and the labeling format defined in them for potential adverse events, testing/performance data, physical testing for balloon catheters, and animal studies. He outlined design controls and regulations that must be performed and certified and the postmarket reporting required on adverse events. Dr. Fearnot listed the causes and precautions against potential risks associated with the device and discussed practice of medicine techniques and special controls that can be used to address these risks. He concluded that the risks of PTCA balloon catheter usage are known, although balloon material is continuing to improve, that the evolution of the practice of medicine, pharmaceutical usage, and the adjunctive devices present a minimal likelihood of new major risks for PTCA, and that special controls have been identified to address and minimize the potential risks.

Lynette Gabriel of the FDA read the FDA questions for panel discussion.

Open Committee Discussion

Mitchell Krucoff, M.D., gave the first panel review. He said that he saw this area as involving anything but a well-understood procedure. He expressed doubt that balloon catheters are such a stable platform that they should be reclassified and asked specifically about design elements not covered under guidance such as tip contour, shaft, and so on. Sponsors replied that although balloon materials are changing, the clinical situation in treating arthroscopic plaque is not, and that manufacturers could address problems of new design elements through design

controls. Dr. Krucoff underlined his concern about new risks involving configurations of new materials, saying that this moving platform presents the possibility of new risks.

Michael Domanski, M.D., gave the second panel review, stating that he supported downclassification and thought that there was substantial advantage to reducing regulatory burdens in areas such as this. He thought the process concerns were well addressed but asked whether new manufacturers would still need to perform clinical and animal studies as well as bench testing to obtain market approval. Dr. Domanski expressed concern that less experienced manufacturers must not be allowed to enter the market with lesser products. **Mr. Dillard of the FDA** clarified that the standard after downclassification would be equivalent safety and efficacy to the current product, which would predominantly require bench testing. Dr. Domanski also suggested revisions to the definition of PTCA catheters and the list of possible risks to health contained in the guidance documents and noted the need for ongoing revisions of those guidances as the technology evolves. With those modifications, he supported downclassification.

Other comments from panel members included whether reclassification should apply to balloon catheters used with new devices for new therapy indications, whether reclassification would lead to unnecessary angioplasties, whether reclassification would lead to less innovation in manufacturing, the need for revisions to the health risks sections and device descriptions in the petition and to the guidance documents, and the need for more careful wording in technical references such as "high-density polymer." **The Consumer Representative, Mr. Robert Dacey**, stressed the primacy of patient safety concerns.

Final Sponsor Comments

The sponsors of the petition had no additional remarks.

Panel Discussion of FDA Questions

1) Does the proposed classification description sufficiently describe the percutaneous transluminal coronary angioplasty (PTCA) catheter?

The panel revised the proposed classification description to read:

"PTCA catheters comprise angiographic systems that operate on the principle of hydraulic pressurization applied through an inflatable balloon attached to the distal end. This includes on the wire and over the wire applications, including rapid exchange devices. A PTCA balloon catheter has a single or double lumen shaft with a balloon near the distal tip. The catheter typically features a balloon of appropriate compliance for the clinical application constructed from a polymer. The balloon is designed to uniformly expand to a specified diameter and length at a specific pressure as labeled, with well-characterized rates of inflation and deflation and well-characterized burst pressure. The device generally features a radiographic marker to facilitate fluoroscopic visualization of the balloon during use."

2) Have the health risks associated with PTCA catheters been adequately identified? If not, what are the additional risks that should be described?

The panel revised the list of identified health risks as follows:

Acute vessel closure
Coronary artery dissection, perforation, rupture
Acute MI (unstable angina was deleted)
Coronary artery spasm

Arrhythmias
Embolization or fragmentation of thrombotic or atherosclerotic or stent material
Hypotension/Hypertension
Stroke
Reaction to contrast agent
Renal failure
Failed procedure
Coagulopathy
Aneurysm formation in the coronary artery
Restenosis
Emergency bypass surgery
Death
Balloon rupture

The panel added the following:
Air embolization
Infection
Emergency surgery for vascular access site complications, retroperitoneal bleeding, guidewire complications, impending MI
Other component device failure

3) Have appropriate special controls been identified to adequately address the risks to health specific to PTCA catheters? If not, what additional special controls are needed for reclassification?

The panel revised the list of proposed special controls to read:

Updated guidance documents
Updated device labeling
Better postmarket surveillance capability to ensure there is no harm to patients
Specific protocol for each bench test
Combination testing such as burst strain testing after deflation

Open Public Hearing

There were no requests to address the panel.

General Device Classification Questionnaire

The panel filled out the questionnaire for PTCA catheters as a life sustaining or life-supporting device of substantial importance in preventing impairment of human health. There was disagreement over whether the device presented a potential unreasonable risk of illness or injury, with the majority voting that it did not. The majority felt that there was sufficient information to establish certain special controls to provide such assurance. The specific special controls were the subject of much panel discussion, with the majority voting for some form of postmarket surveillance to be hammered out by the FDA, guidance documents updated with testing specifications, and revised labeling. The panel agreed that the device should be subject to restricted availability by prescription only, with one member also arguing for restricting the device to use only by persons with specific training or experience in its use.

On the Supplemental Data Sheet, the panel described PTCA catheters as intended for balloon dilatation of a hemodynamically significant coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion and for restoring coronary flow in patients with ST-segment elevation myocardial infarction. There was panel discussion about the third proposed indication for use, balloon dilatation of a stent after implantation, but it was deleted because the panel felt it could be applied to in-stent restenosis, on which there were insufficient data. The panel recommended that the guidance document should be updated to address the issue of tacking up in-stent placements. The panel identified the risks to health presented by the device as discussed in question 2 above, with special controls

as discussed above. The panel voted to recommend classification to class II with medium priority on the basis of presentations given, the day's discussions, and references presented by the petitioners.

On behalf of the FDA, **Jim Dillard** thanked the panel and petitioners for their time and careful review. **Acting Chairperson Dr. Tracy** adjourned the Open Session for the day at 4:30 p.m.

OPEN SESSION—DECEMBER 5, 2000

Acting Panel Chair Dr. Tracy called the meeting to order at 8:07 a.m. **Executive Secretary Megan Moynahan** read the conflict of interest statement, noting that waivers had been granted to Drs. Tracy, Aziz, Krucoff, and Laskey for their past or unrelated interests in matters involving a firm potentially affected by the day's deliberations. She read appointments to temporary voting status for Drs. Tracy, Aziz, Laskey, Simmons, Krucoff, Domanski, and Tracy, and an appointment for Dr. Tracy as Acting Panel Chair. **Dr. Tracy** asked panel members to introduce themselves.

Open Public Hearing

There were no requests to address the panel.

PMA SUPPLEMENT P980051/S1 FOR MEDTRONIC'S MODEL 7250 JEWEL AF

Sponsor Presentation

Marshall Stanton, M.D., of Medtronic described the Model 7250 Jewel AF device and Model 9464 Patient activator, noting that the device was approved in the ventricular tachyarrhythmias/atrial tachyarrhythmias (VT/AT) population in June 2000. The device includes features intended for treatment and prevention of atrial tachyarrhythmias and includes a patient activator and a defibrillator lead. He read the proposed indication for use, which was to provide pacing, cardioversion, and defibrillation for treatment of patients with symptomatic, drug refractory atrial tachyarrhythmias or life-threatening ventricular tachyarrhythmias, saying that device-based therapy is part of an overall treatment strategy for symptomatic and drug refractory patients, those who need more control of their therapy, and those with frequent hospital visits for cardioversions.

Michael Gold, M.D., Ph.D., of the University of Maryland, gave the clinical study results. The study was intended to demonstrate the safety and efficacy of the Model 7250 Jewel AF in patients suffering from symptomatic, drug refractory atrial tachyarrhythmias without ventricular ICD indications. It was a multi-center, prospective follow-up study for safety and efficacy of treatment therapies with a randomized crossover study for evaluation of prevention therapies. Dr. Gold listed the study inclusion and exclusion criteria for the 144 implanted subjects and the follow-up data, as well as patient characteristics. Primary objectives for safety objectives were to estimate the relative risk of complications for the model 7250 compared to the 7219 D model and for efficacy to estimate the efficacy of atrial tachyarrhythmias termination therapies of the model 7250. The primary safety endpoint was complication-free survival, with

the secondary objective being survival from all-cause mortality, as shown by a multivariate Cox proportional hazards regression model adjusted for differences in baseline patient characteristics in the two populations.

Dr. Gold showed that the safety primary endpoint was met and that a comparison of complication free-survival at six months showed no statistically significant different between the two models reported complications are consistent with previous device studies. Of these system/procedure related complications, the greatest were lead dislodgements. Dr. Gold explained the definition of efficacy success/failure of termination therapy and showed that the device met its efficacy objective at 91% efficacy for atrial tachyarrhythmias termination therapies within the appropriate confidence bounds. The data showed a 98.8% positive predictive value for detection of atrial tachyarrhythmias, although prevention therapies on 75 patients produced no significant difference in the frequency of episodes. The study found no incidence of atrial shock induced ventricular tachyarrhythmias or ventricular fibrillation, although a small proportion had spontaneous appropriately detected ventricular episodes.

Secondary objectives and additional analyses showed that the vast majority of patients received only one atrial shock per episode and that the efficacy of atrial shock therapy for atrial fibrillation was very high. Efficacy of patient-activated shocks was also very high. Dr. Gold presented data on pacing efficacy and data on impact on quality of life that showed an increase in quality of life over time, with most areas significantly improving. The frequency and severity of symptoms also significantly decreased over the course of the study and out to six months. The

mortality data showed good survival rates. Dr. Gold also presented data on the use of the 9464 patient activator, showing that patients consistently used the patient activator over time, and on the 6937A lead patient experience.

David Schwartzman, M.D., presented clinical vignettes from his own practice to show that the device when used with antiarrhythmic drugs provides relief of disability. Two patients also addressed the issue of patient-commanded shock. The first, **Jane Jones,** had had the device for 13 months and stated that she found the device easy to operate, that it was preferable to cardioversion, and that it allowed her greater independence and freedom. **Donald Carlson** had the device implanted 14 months ago and stated that he felt the device allowed him freedom from hospital stays and ability to go anywhere.

FDA Presentation

Doris Terry, lead reviewer, acknowledged the members of the FDA review team. She explained the function of the device, which is to detect and treat episodes of atrial and ventricular tachyarrhythmias and bradycardia by delivering defibrillation, cardioversion, antitacyarrhythmic pacing, or bradycardia pacing. Atrial arrhythmias are detected by the model as either AF or AT by monitoring the cycle lengths and regularity of the atrial intervals. She noted this device is the first of its kind in the AF population. The system components are the pulse generator Model 7250, the Model 9465 patient assistant, the model 6937 A lead, and other commercially available leads.

Ms. Terry read the indications for use and noted that sponsors had already described the study design. She described the population of 146 patients, 97% of whom had a primary indication of AT/AF only and most of whom were NYHA class I or class II, with a mean ejection fraction of 51.1%. Data analysis looked at time to first system-related complication, results compared to the Model 7219D, and episode treatment effectiveness, using a generalized estimating equation. Ms. Terry listed type and definition of adverse events and summarized them as system-related or nonsystem-related. She presented complication-free survival rates based on Kaplan-Meier estimates at three and six months and survival data at three and six months, and she noted that there were eight deaths during the study. Episode treatment effectiveness for atrial tachyarrhythmias fell within the required range and confidence bounds. Effect of prevention therapies on frequency of atrial tachyarrhythmias, however, found no statistically significant difference in frequency of reduction in a randomized crossover assignment.

Ms. Terry noted that the model 9464 patient activator is a handheld device that is a downsized model of the model 9465 patient assistant. 71% of patients were programmed with self-activated shocks, which showed an effectiveness rate of 89.1 %. There were 27 total adverse events related to the patient activator. The Model 6937A SVC/CS Lead was implanted in 114 patients, with the lead parameters stable through three months. There were four lead-related adverse events. Ms. Terry then read the panel questions.

Open Committee Discussion

Tony W. Simmons, M.D., was the lead panel discussant. He stated that he had a number of problems with the proposal. One involved the number of adverse events and the number of serious complications involving non-implanted patients, lead dislodgements, and infections. He asked whether a 15% complication rate is realistic for patients who do not have a life-threatening disease but must undergo multiple operations for these adverse events. Dr. Simmons contended that the risk/benefit ration was still too high given the reoperation rate and was unsure that the device would be applied to that selected group who can make it work.

Dr. Simmons noted that the atrial lead dislodgement rate was significantly higher than in the reported literature rate and recommended a notation in the labeling on the high rate of lead dislodgement. Dr. Simmons also stated that this is a device for atrial fibrillation, not atrial flutter and should not be described as a treatment for that group. He stressed highlighting the warning that patients receiving AV nodal ablation should have the atrial ATP and atrial high frequency burst therapies disabled.

Other panel comments included the need for patients to be on an anticoagulation treatment regimen that should be specified in the labeling. While some commented on the positive effect on quality of life for a select group of patients, others expressed significant safety concerns and noted the discouraging finding that anti-tachyarrhythmia pacing does not prevent atrial fibrillation. It was reiterated that the warning that patients receiving an AV nodal ablation after implant should have the atrial ATP and atrial high frequency burst therapies disabled should be put in bold and noted on parts of the device. Other concerns involved patient difficulty in

understanding the device and the need to make the device workable for the hearing-impaired or less educated populations. Concerns were expressed on the lead dislodgement rate. Clarification was requested on the definition of chronic atrial fibrillation versus persistent or incessant atrial fibrillation. One member noted that this is a very complex device with an exciting potential but that the data could be read in a number of ways. There was discussion on how to tease out the risk/benefit ratio other than with a randomized controlled trial powered for safety. The Consumer Representative recommended making the patient labeling as simple as possible and making one-on-one skill training a component of patient education.

FDA Questions to the Panel

1. *Please discuss the clinical significance of the complication-free survival results and the occurrence of stroke in assessing the safety of the Jewel AF for the new indication of treating patients with atrial tachyarrhythmias.*

The panel recommended labeling guidelines to indicate that a course of anticoagulation should be followed according to medical standards. Labeling should indicate that the device should be deactivated if stroke or transient ischemic attack occurs. There should be postmarket surveillance for occurrence of stroke in a matched cohort. Patient education materials should instruct the patient to notify their doctor if a stroke occurs.

2) Given this choice of controls, do the clinical results of the Jewel AF Only study demonstrate device safety for the intended patient population?

The panel concluded that the results do not demonstrate danger or safety in any global comparison to populations other than ventricular defibrillation patients. The ultimate issue was a comparison to population with atrial fibrillation. In the absence of an appropriate set of controls, the panel deemed an informed judgment of safety to be impossible. An analysis of risk of death related to ejection fraction and other variables was requested.

3) Based on the effectiveness results, please discuss whether you believe the potential benefits of atrial tachyarrhythmia termination and prevention therapies outweigh the risks of implanting the Jewel AF in the intended patient population.

The panel thought the effectiveness results presented showed the potential benefits outweigh the risks and that reasonable safety was demonstrated, but stressed that the warning about use of ATP in antinodal-ablation should be highlighted on everything built into the programmer.

4) *Do you have any comments or concerns regarding the clinical use and labeling of the Model 9465?*

The panel thought the device was not self-explanatory and should be reconfigured for device simplicity, patient ergonomics, and user friendliness. The Consumer Representative stressed the need for one-on-one skill training and for repeat training as often as necessary.

5) *Please discuss whether you believe that the potential benefits of implanting the Jewel AF in patients with atrial tachyarrhythmias outweigh the possible risks associated with the implantation and therapies of the device.*

The panel thought this question less important in light of other considerations brought up in the discussion. Effectiveness was addressed in terms of terminating atrial fibrillation.

6a) Please comment on whether you believe the Jewel AF provides adequate AF prevention and/or treatment therapy for patients having an ablation and whether the therapies particularly for atrial shock may be poorly tolerated in some patients.

The panel thought the device provides adequate treatment therapy in terms of terminating AF, although its effects in terms of prevention pacing were not significantly beneficial. They thought the therapies were tolerated well enough.

6b) Please discuss how clinical information on potential intention to treat failures should be presented in the Jewel AF's instructions for use in labeling.

This information on the intent-to-treat patients should be clearly stated in the clinical section of the labeling to show patients and clinicians why the procedure might not work out for prospective patients.

7) Please provide your clinical impression of the proposed indications for use and comments on whether they are clinically appropriate for the indicated population.

After a brief discussion on the wording involving drug-refractory fibrillation, the panel revised the indications for use as follows:

> The Jewel AF system is intended to provide pacing, cardioversion and defibrillation and should be limited to patients with symptomatic, drug-refractory atrial fibrillation and/or life threatening ventricular tachyarrhythmias.

Open Public Hearing

There were no requests to address the panel.

Closing Sponsor Comments

The sponsors thanked the panel for their comments on the labeling.

Closing FDA Comments

There were no closing remarks from the FDA representatives.

Executive Secretary Megan Moynahan read the voting options and instructions.

A motion was made and seconded to recommend the PMA as approvable subject to the following conditions:

A warning should be added to the labeling about the need for an anticoagulation protocol consistent with current medical guidelines.

A more specific warning about the lack of backup during AV nodal ablation should be added to the labeling.

A statement should be added to indicate that no significant added benefit of pacing algorithms was demonstrated.

The significant amount of lead dislodgement during trials should be noted.

References to atrial tachyarrhythmias should be changed to atrial fibrillation.

Existing data should be stratified if possible on underlying conditions and their relationship to deaths, strokes, and VT/VF.

Warnings should be added on the anti-tachyarrhythmia pacing and the lack of brady backup.

Patient education on device use should be expanded and one-on-one training on activation should be instituted.

A warning should be added on device deactivation during TIA or CVA to prevent shocks in temporal conjunction to neurological events.

There should be postmarket surveillance on results when an anticoagulation protocol is followed in a postmarket cohort of 100-150 patients, on the high lead complication rate and whether certain lead configurations have a higher chance of dislodgement, on risks of VT/VF, death and stroke and whether there is a proven benefit to decreasing fibrillation thresholds.

The motion to recommend the PMA as approvable subject to the above conditions was passed unanimously.

Acting Panel Chairperson Dr. Tracy adjourned the meeting at 2:05 p.m.

I certify that I attended the Open Session of the Circulatory Systems Devices Panel Meeting on December 4-5, 2000, and that this summary accurately reflects what transpired.

Megan Moynahan.
Executive Secretary

I approve the minutes of this meeting as recorded in this summary.

Cynthia M. Tracy, M.D.
Acting Chairperson

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